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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/204,865	12/03/1998	JER-KANG CHEN	9584-006-999	9457

11/20/2002
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/20/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/204,865

Applicant(s)

Chen et al.,

Examiner

Frank Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 26, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 13-15, 21-23, 26-32, 35, 36, 40, 41, 44, 50-52, 60, and 64-83 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 11, 13-15, 21-23, 26-32, 36, 40, 41, 44, 50-52, 60, 64-67, and 72 is/are allowed.
- 6) ☒ Claim(s) 35, 68-71, and 78-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on August 26, 2002 has been entered as Paper No: 25. The claims pending in this application are claims 1-8, 11, 13-15, 21-23, 26-32, 35, 36, 40, 41, 44, 50-52, 60, and 64-77 will be examined. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 35 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 79 are rejected as vague and indefinite because it is unclear how any kind of three-dimensional porous substrate has a void volume. Note that it is known that the void volume is defined as the volume of mobile phase in a column having a resin comprising beads. However, independent claims 1, 60, and 68-77 do not limit claimed flow-through device as a column having a resin comprising beads. A paper with multiple pores can be considered as a flow-through device without a void volume since it has length, width and height. Please clarify.

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 68, 78, and 80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Ness *et al.*, (US Patent No. 5,667,976, published on September 16, 1997).

Van Ness *et al.*, teach solid supports for nucleic acid hybridization assay. They showed that an oligonucleotide was covalently immobilized onto a polymer-coated solid support or similar structure such as polypropylene beads as recited in claim 78. The oligonucleotides could also be linked to the beads via its 5' or 3'-terminal residue as recited in claim 80. The beads or similar structures could be employed free in solution or in a flow-through format, such as in a column. The column filled with polypropylene beads was considered as a flow-through device as recited in claim 68 wherein the column was considered as a housing as recited in claim 81. The resultant covalently immobilized oligonucleotides on the support was served as nucleic acid probes, and hybridization assays were conducted wherein specific target nucleic acids were detected in complex biological samples as recited in claim 82 (see abstract, columns 2-4, 7, and 8).

Therefore, Van Ness *et al.*, teach all limitations recited in claims 68, 78, and 80-82.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ness *et al.*, (September 16, 1997) as applied to claims 68, 78, and 80-82 above, and further in view of Beattie (US Patent No. 5,843,767, filed on April 10, 1996).

The teaching of Van Ness *et al.*, has been summarized previously, *supra*.

Van Ness *et al.*, did not disclose a flow-through device having polypropylene beads with immobilized capture polynucleotide about 6×10^{-17} to 6×10^{-16} nmol/nm².

Beattie teaches to tether DNA targets or probes for hybridization using nanochannel glass (NCG) wafers. NCG materials were unique glass structures containing a regular geometric array of parallel holes or channels as small as 33 nm in diameter or as large as several micrometers in

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diameter. These nanochannel glass structures could possess packing densities in excess of 3×10^{10} channels per square centimeter, fabricated in various array configurations (column 9, eighth paragraph). A variety of materials could be immobilized or fixed to the glass surfaces within the channels of the NCG array, to yield a high surface area to volume ratio. Once the fabrication process was complete, the NCG material was wafered perpendicular to the direction of the channels with a diamond saw and then polished to produce 0.1-1.0 mm sections of material (0.1-1 mm thick) (column 10, second paragraph). 5' or 3' terminal residue of said capture polynucleotide could be attached to the porous substrate via a linker (see column 16, second and third paragraphs). Although Beattie did not directly teach that the three-dimensional porous substrate had about 6×10^{-17} to 6×10^{-16} nmol/nm² of a capture polynucleotide (about 3.6×10^{12} to 3.6×10^{13} probe per square centimeter) as recited in claim 69, they taught that, for DNA binding capacity, the amount of attaching labeled oligonucleotide to flat glass and gold surface were up to 10^8 probe in a $50 \mu\text{m}$ and $50 \mu\text{m}$ area (4×10^{12} probes per square centimeter as recited in claims 69) (see column 17, third paragraph).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a flow-through device having polypropylene beads with immobilized capture polynucleotide about 6×10^{-17} to 6×10^{-16} nmol/nm² in view of the prior art of Van Ness *et al.*, and Beattie. One having ordinary skill in the art would have been motivated to modify the method of Van Ness *et al.*, because incorporation of different amount of a polynucleotide into a three-dimensional porous substrate was well known in the art at the time the invention was made and the simple

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replacement of one three-dimensional porous substrate (ie., NCGwafers) with known properties with another three-dimensional porous substrate (ie., polypropylene beads) with known properties for incorporating the same amount of polynucleotides would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

8. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamb *et al.*, (US Patent No.6,060,240, filed on December 13, 1996).

Kamb *et al.*, teach the generation of beads comprising capture oligonucleotides or nucleic acids. Beads included commercially available nucleoside-derivatized CPG, polystyrene beads, magnetic beads, and polystyrene beads grafted with polyethylene glycol as recited in claim 69(column 10, third paragraph). Capture oligonucleotides could be attached to a bead for use (see column 11, fourth paragraph). The capture oligonucleotides could also be linked to the beads via a phosphodiester linkage to the phosphate of the 3'-terminal nucleotide via nucleophilic attack by

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a hydroxyl (typically an alcohol) on the bead surface; or via a phosphoramidate linkage between the 3'-terminal nucleotide and a primary amine conjugated to the bead surface (column 12, fourth paragraph). The column filled with the beads could be considered as a flow-through device.

Although Kamb *et al.*, did not directly show that the three-dimensional porous substrate had about 6×10^{-17} to 6×10^{-16} nmol/nm² of a capture polynucleotide (about 3.6×10^{12} to 3.6×10^{13} probe per square centimeter) as recited in claim 69, they taught that the number of capture oligonucleotides that could be attached onto the surface of a 10 micron radius bead (their surface was roughly 1200 square microns) were about 3×10^9 ($\sim 2.5 \times 10^{14}$ probe per square centimeter).

However, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made a flow-through device having polypropylene beads with immobilized capture polynucleotides about 6×10^{-17} to 6×10^{-16} nmol/nm² in view of patents of Kamb *et al.*. One having ordinary skill in the art has been motivated to modify the flow-through device of Kamb *et al.*, because optimization of amount of a polynucleotide incorporated on a three-dimensional porous substrate would have been obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to adjust amount of a polynucleotide incorporated on a three-dimensional porous substrate. Note that where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (see MPEP 2144.05).

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9. Claims 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ness *et al.*, (September 16, 1997) as applied to claims 68, 78, and 80-82 above, and further in view of Chamberland (Canadian Patent 1,110,511, issued on November 13, 1981).

The teachings of Van Ness *et al.*, has been summarized previously, *supra*. Van Ness *et al.*, also teach to incorporate polynucleotides onto a membrane (see column 3).

Van Ness *et al.*, do not disclose to incorporate polynucleotides onto a membrane about 1 mm to 20 mm thick with an average pore size of about 10 to 100 μm as recited in claims 70 and 71.

Chamberland teach an unidirectional fluid membrane. The membrane was in the form of a sheet of porous plastic material comprising a multitude of interconnected pores that together define passages suitable to allow a gas such as air to flow (abstract). The membrane which was in the form of a sheet of porous plastic material could be made of polypropylene or polyethylene (page 6, lines 25-28) with thickness ranging from about 1/16 to 1/2 inch (~1.6 mm to 12.7 mm) and a interconnected pore size ranging from 8 to 250 μm as recited in claims 70 and 71.

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a flow-through device comprising a three-dimensional porous substrate composed of polypropylene or polyethylene membrane about 1 mm to 20 mm thick with an average pore size of about 10 to 100 μm in view of the prior art of Van Ness *et al.*, and Chamberland. One having ordinary skill in the art would have been motivated to modify the flow-through device of Van Ness *et al.*, because the simple replacement of one kind of membrane with known properties with another kind of

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membrane (ie., three-dimensional porous polypropylene or polyethylene membrane) with known properties for incorporating polynucleotides would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

10. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ness *et al.*, (September 16, 1997) as applied to claims 68, 78, and 80-82 above, and further in view of MacConnell (US Patent No. 4,787,963, published on November 29, 1988).

The teachings of Van Ness *et al.*, has been summarized previously, *supra*. Van Ness *et al.*, teach 30 min hybridization (see Examples 3 and 4 in columns 17 and 18).

MacConnell showed that, in the case of short synthetic nucleic acid probes, hybridization reactions could be completed in less than 15 minutes if high concentrations of oligomeric probe, were used along with rate enhancer compounds (see column 3).

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Both Van Ness *et al.*, and MacConnell do not teach the hybridization of a capture polynucleotide to a target nucleic acid in less than one minute.

However, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have performed a hybridization assay in less than one minute in view of patents of Van Ness *et al.*, and MacConnell. One having ordinary skill in the art has been motivated to modify the methods of Van Ness *et al.*, and MacConnell because optimization of the hybridization time during a hybridization assay would have been obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to adjust the hybridization time during the process of a hybridization assay. Note that where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (see MPEP 2144.05).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Claims 1-8, 11, 13-15, 21-23, 26-32, 35, 36, 40, 41, 44, 50-52, 60, 64-67, and 72-77 are allowed over prior art.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

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Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
November 18, 2002


ETHAN C. WHISENANT
PRIMARY EXAMINER